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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,965	05/24/2001	John Hiscott	A33606-PCTUS	7406

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EXAMINER	
GARVEY, TARA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,965	HISCOTT ET AL.	
	Examiner	Art Unit	
	Tara L. Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-21,26,32 and 34-39* is/are pending in the application.

4a) Of the above claim(s) *3, 8-16 and 35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,17,18 and 39* is/are rejected.

7)☒ Claim(s) *6,7,19-21,26,32 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20051215*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 3,5-21,26,32 and 34-39 are pending. Receipt is acknowledged of an amendment filed on December 16, 2005 in which claims 5-7, 17-21, 26, 34 and 39 were amended and claim 4 was canceled.

Response to Amendment

Claim Rejections - 35 USC § 102

The rejection of claims 5 and 39 under 35 U.S.C. 102(b) as being anticipated by Yoneyama et al (Applicant reference CY, published Feb, 1998) is withdrawn in view of applicant's amendment.

The rejection of claims 4, 5, 17-18, and 39 under 35 U.S.C. 102(a) as being anticipated by Au et al (Applicant reference AC) is withdrawn in view of applicant's amendment.

New grounds of rejection

This new rejection is necessitated by applicant's amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 17, 18 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au et al (The Journal of Biological Chemistry (1998) volume 273(44), pages 29210-29217; Applicant reference AC).

Au et al teach a cellular extract comprising IRF-7H (Figure 4 and Experimental Procedures section), which reads on isolated because isolated interpreted as broadly as is reasonable reads on any level of removal of the protein from its natural location in the cell, and which reads on IRF-7 because it is an IRF-7 protein from an alternatively spliced IRF-7 transcript. The IRF-7 was isolated from NDV-infected cells and thus reads on comprising at least one modified serine or threonine phosphoacceptor site, wherein the modification causes cytokine gene activation for the following reasons. As taught by the abstract and at page 29213, column 2, overexpression of IRF-7 results in an activation of IFNA promoter in transient transfection assay and a strong enhancement of virus-mediated activation of this promoter. Because the IFNA promoter is a cytokine promoter, then IRF-7 that is exposed to virus increases cytokine

expression. The reference teaches that no significant enhancement of virus-mediated stimulation of IFNA4 promoter was detected in cells cotransfected with the mutants of IRF-7 that have the carboxyl-terminal parts of the peptide deleted, and that these data indicate that the carboxyl-terminal part of IRF-7 is a target for the virus-mediated modification of IRF-7 (page 29213, column 2). Au et al also teach that the phosphorylation sites (in the serine-rich region of the carboxyl-terminus) seem to be required for the observed synergy between virus and IRF-7H in the activation of the IFNA promoter, which was observed only with the full-length IRF-7H but not with its carboxyl-terminal deletion mutants (page 29216, bottom of column 2). These teachings show that the isolated IRF-7H from virus infected cells taught by Au et al is IRF-7 that has phosphorylation modifications in the carboxyl-terminus and thus reads on the claimed inventions.

Regarding which serine residues are modified, based upon the location of the serines, and the teachings of Au et al, Lin et al (described in the arguments in the previous office action mailed June 28, 2005) and the instant specification, it appears that the phosphorylation of IRF-7H is inherently at Ser-477 and/or Ser-479.

Au et al does not specifically teach a modified isolated IRF-7A protein. In regard to an IRF-7A protein, Au et al teaches that IRF-7A and IRF-7H are IRF-7 splice variants. Specifically, IRF-7H has 18 amino acids in its N-terminal region that are not present in IRF-7A (page 29211, right column, third full paragraph and page 29212, Figure 1). Further, two transcripts of 2.6 and 2.0 kB are detected in all IRF-7 positive northern blot samples and it is unknown which transcript is IRF-7H, but IRF-7H and IRF-7A are

message is present in equal amounts. During NDV infection of human PBLs, the ratio of IRF-7H/IRF-7A was maintained (page 29211, right column fifth full paragraph to page 29212, left column). Analysis of IRF-7H revealed a transactivation domain in the carboxy-terminal half of the protein and this sequence is also present in IRF-7A. Therefore, Au et al suggest that the IRF-7A variant is also expected to activate transcription as well (page 29212, left column, first full paragraph to page 29213, left column). Further, an additional regulatory region in the carboxy-terminus of IRF-7H that contains a serine–rich region is also present in IRF-7A (page 29216, right column). Thus, the regions in the carboxy-terminus of IRF-7H that are modified in response to viral infection and that are responsible for activation of the IFNA promoter are also present in IFN-7A

It would have been obvious to one of ordinary skill in the art to modify the teachings of Au et al to produce a modified IRF-7A protein that is capable of increased cytokine gene activation because Au et al teach that it is within the ordinary skill in the art to produce a modified IRF-7H protein that increases IFNA expression by exposure to a virus and because Au et al further contemplated that a viral infection will modify the other splice variants such as IRF-7A in the same manner since the sequences that are modified and responsible for IFNA gene activation are present in IRF-7A. One would have been motivated to do so in order to receive the expected benefit, as suggested by Au et al, of characterizing the IRF-7A splice variant. Absent of any evidence to the contrary, there would have been reasonable expectation of success in having an isolated IRF-7A protein with a modified serine or threonine phosphoacceptor site that is

capable of increased cytokine gene activation because the prior art has already contemplated that IRF-7A will be modified in the same manner and have the same functional ability as IRF-7H.

Allowable Subject Matter

Claims 6, 7, 19-21, 26, 32 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's

PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey, Ph.D.
Examiner
Art Unit 1636

TLG

CELINE QIAN, PH.D.
PRIMARY EXAMINER